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**UNITED STATES DISTRICT COURT  
DISTRICT OF NEW JERSEY**

UNITED STATES OF AMERICA,

*Plaintiff(s),*

v.

**Undetermined quantity of Relumins Advanced Glutathione kits**, each kit containing an outer box, an individual box of Relumins Advanced Glutathione lyophilized powder, an individual box of Relumins Vitamin C 500mg, a bottle of Relumins Advance White Glutathione Booster capsules, and product insert labeled in part:

(outer box) :

“\*\*\*RELUMINS ADVANCED GLUTATHIONE mg Lyophilized Glutathione with Advanced Glutathione Boosters\*\*\*vials + \*\*\*diluent ampoules + 30 Capsules \*\*\*For Oral, IM&IV\*\*\*Reconstitute with 5ml Vitamin C Solution\*\*\*Relumins Labs, 183 Locust Ave, West Long Branch, NJ 07764 [www.relumins.com](http://www.relumins.com)\*\*\*”;

(box)

“\*\*\*Relumins-Advanced Glutathione mg Relumins Labs, 183 Locust Ave, West Long Branch, NJ 07764 [www.relumins.com](http://www.relumins.com) 1-732-781-1488\*\*\*vials\*\*\*”;

HON.

*Civil Action No.*

VERIFIED COMPLAINT  
FOR FORFEITURE *IN REM*



(vial)

\*\*\*\*Relumins-Advanced Glutathione mg Every vial contains: Glutathione powder mg Relumins Labs, 183 Locust Ave, West Long Branch, NJ 07764 [www.relumins.com](http://www.relumins.com) \*\*\*\*;

(box)

\*\*\*\*Vitamin C 500 mg\*\*\*\*Relumins Labs, 183 Locust Avenue, West Long Branch, NJ 07764 \*\*\*[www.relumins.com](http://www.relumins.com)\*\*\*\*;

(loose, clear ampoules)

\*\*\*\*Solvent for Glutathione\*\*\*\*Vitamin C 500mg 5ml Relumins Labs\*\*\*\*West Long Branch \*\*\*[www.relumins.com](http://www.relumins.com)\*\*\*\*;

(bottle)

\*\*\*\*RELUMINS ADVANCE WHITE Glutathione Booster\*\*\*\*30 Vegetarian Capsules\*\*\*\*;

(product insert)

“GLUTATHIONE RELUMINS Reduced Glutathione Powder for Injection Parenteral Use Only\*\*\*\*INDICATIONS\*\*\*\*prevention of cisplatin-induced neurotoxicity\*\*\*\*”;

**123 Tatiomax Glutathione Collagen :**

**Whitening kits**, more or less, each kit containing 10 vials of Tatiomax 1200mg Reduced Glutathione and 200mg Hydrolyzed Collagen powder for injection, 10/2 ml ampoules of Vitamin C 500mg, 10/5ml ampoules of Sterile Water for Injection, and product insert labeled in part:

(box)

\*\*\*\*REDUCED GLUTATHIONE + HYDROLYZED COLLAGEN\*\*\*\*TATIOMAX\*\*\*\*1200MG REDUCED GLUTATHIONE 200 MG HYDROLYZED COLLAGEN/VIAL POWDER FOR INJECTION \*\*\*I.M./I.V. ANTIDOTE\*\*\*10 VIALS\*\*\*  
Manufactured By SUJIE PHARMACEUTICAL LTD TOYKO JAPAN\*\*\*;



(clear vials)

\*\*\*TATIOMAX 1200MG REDUCED  
GLUTATHIONE 200 MG HYDROLYZED  
COLLAGEN/ VIAL POWDER FOR INJECTION  
\*\*\*IM/IV\*\*\*;

(box)

\*\*\*Vitamin C Injection\*\*\*50 x 2 mL Ampoules  
\*\*\*Each 2 mL ampoule contains Ascorbic Acid USP  
500 mg\*\*\*FOR INTRAMUSCULAR OR  
INTRAVENOUS INJECTION

\*\*\*Manufactured by: T.P. Drug  
Laboratories \*\*\*Co. LTD.\*\*\*98 Soi Sukhumvit  
62,Yak 1,Bangchak, Prakanong, Bangkok 10260,  
Thailand\*\*\*;

(brown ampoules)

\*\*\*Vitamin C injection 2 CC Ascorbic acid 500 mg  
T.P. DRUG\*\*\*

(box)

\*\*\*RX STERILE WATER FOR INJECTION\*\*\*  
PARENTERAL\*\*\*50 ampoules x 5mL\*\*\*  
Manufactured and Distributed by: EURO-MED®  
LABORATORIES PHIL., INC. Km. 36 Gen. Emilio  
Aguinaldo Highway Dasmarinas, Cavite,  
Philippines\*\*\*;

(clear, loose ampoules)

\*\*\*5 ml STERILE WATER FOR INJECTION\*\*\*;

(product insert)

"TATIOMAX 1200mg/vial Powder for Injection IM/IV  
ANTIDOTE\*\*\*INDICATIONS Different alcoholic  
liver diseases\*\*\*";

and

**All Saluta Glutathione Whitening kits**, each kit  
containing 10 vials of RX Glutathione Saluta 600mg  
powder for Injection, 10/2ml ampoules of Vitamin C  
500mg, 10/5ml ampoules of Sterile Water For  
Injection, and product insert labeled in part:



(box) :

“\*\*\*RX Glutathione Saluta\*\*\*600mg/Vial Reduced  
Glutathione Powder for Injection \*\*\*Parenteral Use  
Only\*\*\*i.m./i.v.\*\*\* Manufactured by: Shandong  
Luye Pharmaceutical Co Ltd., Yantai, Shandong,  
PRC\*\*\*”;

(vials) :

“\*\*\*Glutathione Saluta\*\*\*600mg Reduced  
Glutathione Powder for Injection\*\*\*”;

(box)

“\*\*\*Vitamin C Injection\*\*\*50 x 2 ml  
Ampoules\*\*\*Each 2 mL ampoule contains  
Ascorbic Acid USP 500 mg\*\*\*FOR  
INTRAMUSCULAR OR INTRAVENOUS INJECTION  
\*\*\*Manufactured by: T.P. Drug Laboratories \*\*\*Co.  
LTD\*\*\*98 Soi Sukhumvit 62,Yak 1,Bangchak,  
Prakanong, Bangkok 10260, Thailand\*\*\*”;

(brown ampoules) :

“\*\*\*Vitamin C injection 2 CC Ascorbic acid 500 mg  
T.P. DRUG\*\*\*”;

(box) :

“\*\*\*RX STERILE WATER FOR INJECTION\*\*\*  
PARENTERAL\*\*\*50 ampoules x 5mL\*\*\*  
Manufactured and Distributed by: EURO-MED®  
LABORATORIES PHIL., INC. Km. 36 Gen.  
Emilio Aguinaldo Highway Dasmarinas, Cavite,  
Philippines\*\*\*”;

(clear, loose ampoules) :

“\*\*\* 5 ml STERILE WATER FOR INJECTION \*\*\*”

(product insert) :

“GLUTATHIONE Saluta Reduced Glutathione  
Powder for Injection Parental Use Only :  
\*\*\*INDICATIONS Antidote\*\*\*prevention of  
Cisplatin-induced neurotoxicity\*\*\*”;

and





**All Laroscorbine Platinum Vitamin C With Collagen kits**, each kit containing 10/5mL ampoules of Laroscorbine Injectable solution labeled in part:

(box)

\*\*\*Laroscorbine Platinum\*\*\*Vitamin C 1 gm  
Collagen 0.35 gm\*\*\*Solution injectable I.V. \*\*\* 10  
ampoules de 5mL \*\*\*Roche\*\*\*;

and

**All labeled boxes**, each box containing bottles of 60/290mg capsules of an article of drug, labeled, in part:

(boxes)

\*\*\*LingZhi Plus\*\*\*290mg x 60 Capsules  
\*\*\*Distributed by: Essence Master in Tortola,  
British Virgin Islands\*\*\* Product of China\*\*\*;

and

all other quantities of an article of drug, labeled listed in the caption, in any strengths or dosages, including packaging and labeling, on the premises of Flawless Beauty LLC, 1215 Main Street, Asbury Park, New Jersey, 07712-6375; RDG Imports LLC, 800 5th Avenue, Asbury Park, New Jersey, 07712-6375.

**DEFENDANTS IN REM.**

Plaintiff, United States of America, by its attorney, Paul J. Fishman, United States Attorney for the District of New Jersey, by Anthony J. LaBruna, Assistant United States Attorney, brings this verified complaint and alleges as follows in accordance with Supplemental Rule G(3) of the Federal Rules of Civil Procedure:



**NATURE OF THE ACTION**

1. This is a civil *in rem* action filed by the United States of America to seize and condemn the articles of drug, as defined by 21 U.S.C. § 321(g)(1), set forth in the above caption (hereinafter “defendant articles”), for violations of the Federal Food, Drug, and Cosmetic Act (“the Act”), 21 U.S.C. § 301 *et seq.*

**THE DEFENDANTS IN REM**

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2. The defendant articles consists of all articles of drugs, whether labeled, in any size or type of container, and in whatever strength or dosage, in the possession of Flawless Beauty LLC, 1215 Main Street, Asbury Park, New Jersey 07712-6375, or RDG Imports LLC, 800 5<sup>th</sup> Avenue, Asbury Park, New Jersey 07712-6375; or elsewhere within the jurisdiction of this Court.

**JURISDICTION AND VENUE**

3. Plaintiff brings this action *in rem* in its own right to condemn and forfeit the defendant articles. This Court has jurisdiction over an action commenced by the United States under 28 U.S.C. § 1345 and 21 U.S.C. § 334.

4. This Court has *in rem* jurisdiction because the defendant articles, in whole or in part, are located in this District.

5. Venue is proper in this District pursuant to 28 U.S.C. § 1395(b) and 21 U.S.C. § 334(a)(1) because the defendant articles are located at Flawless Beauty LLC, 1215 Main Street, Asbury Park, New Jersey 07712-6375, and RDG Imports LLC, 800 5<sup>th</sup> Avenue, Asbury Park, New Jersey 07712-6375.



6. Upon the filing of this complaint, the plaintiff requests that the Court issue an arrest warrant *in rem* pursuant to Supplemental Rule G(3)(b), which the plaintiff will execute upon the articles pursuant to Supplemental Rule G(3)(c).

**BASIS FOR FORFEITURE**

7. The defendant articles are drugs within the meaning of the Act, 21 U.S.C. § 321(g)(1)(B), because all of the defendant articles are intended for use in the

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diagnosis, cure, mitigation, treatment and prevention of disease in man. Certain of the defendant articles (Relumins Advanced Glutathione kit; Tatiomax Glutathione Collagen Whitening kit; Saluta Glutathione Whitening kit; and Laroscorbine Platinum Vitamin C with Collagen kit) are also drugs within the meaning of 21 U.S.C. § 321(g)(1)(C), because they are intended to affect the structure or function of the body.

8. The defendant articles are new drugs within the meaning of 21 U.S.C. § 321(p), because they are not generally recognized by qualified experts as safe and effective under the conditions of use recommended or suggested in their labeling, and they may not be distributed in interstate commerce unless each is the subject of an approved new drug application or exempt from that requirement by an effective investigational new drug application, 21 U.S.C. § 355(a). There are no such approved applications or exemptions from such requirements in effect for the articles described in the caption, 21 U.S.C. § 355(b) or (i) or (j).

9. The defendant articles are misbranded under section 21 U.S.C. § 352(f)(1) because they do not contain adequate directions for use, and, adequate directions



cannot be written so that a layman can use these products safely for their intended uses. The products are not exempt under 21 C.F.R. §§ 201.100(c)(2) and/or 201.115 from the requirement that their labeling bears adequate directions for use because all of the articles lack approved applications.

10. The defendant articles are also misbranded under section 21 U.S.C. § 352(o) because they were manufactured, prepared, or processed in an establishment not duly registered under 21 U.S.C. § 352(o).

11. By reason of the foregoing, the defendant articles are held illegally within the jurisdiction for this Court and are liable to seizure and condemnation pursuant to 21 U.S.C. § 334.

### **FACTS**

12. Flawless Beauty LLC (hereinafter "Flawless Beauty") is an importer, repacker, relabeler, and distributor of the defendant articles and other FDA regulated products.

13. RDG Imports LLC (hereinafter "RDG") is an importer of articles marketed, sold, and distributed by Flawless Beauty.

14. Flawless Beauty and RDG are located in the same building but have separate addresses in Asbury Park, NJ.

15. The U.S. Food and Drug Administration ("FDA") conducted an inspection at Flawless Beauty on March 24, 27, 31, April 7, 17, and May 7 and 16, 2014. FDA inspected RDG on April 17, 2014. During these inspections, FDA investigators observed Flawless Beauty and RDG import various unapproved injectable drugs,





purported to be sterile, from foreign manufacturers. Additionally, three of the products observed at the facility are on FDA Import Alert #66-41 (Detention Without Physical Examination of Unapproved New Drugs promoted in the United States) Tatiomax, RX Sterile Water for Injection, and T.P. Drug Laboratories Vitamin C 500MG for Injection because they are unapproved new drugs.

16. The defendant articles are marketed with claims which demonstrate that they are intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals and are drugs under 21 U.S.C. § 321(g)(1)(B). For example, the LingZhi Plus capsules include disease claims such as “Anti-Cancer” “Anti-Ageing [sic]” “Alzheimer’s [sic] Support” and state that “LingZhi may possess anti-tumor, immunodulatory and immunotherapeutic activities.”

17. In addition to disease claims, some of the defendant articles are marketed with claims that the articles affect the structure or function of the body, causing them to be drugs under 21 U.S.C. § 321(g)(1)(C). For example:

- **Relumins Advanced Glutathione kit:** “Is indicated as an adjunct-treatment for the prevention of cisplatin-induced neurotoxicity and other platinum-based chemotherapeutic agents;” “Current clinical and published studies suggest the therapeutic role of Glutathione for the treatment of alcohol-associated liver diseases (alcoholic fatty liver, alcoholic liver fibrosis, alcoholic liver cirrhosis, and acute alcoholic hepatitis);” “Has been used clinically to treat degenerative brain [and]



liver diseases including Parkinson's [sic];" and "Whitens, repairs [and] rejuvenates skin."

- **Tatiomax Glutathione Collagen Whitening kit:** "Different alcoholic liver diseases (alcoholic fatty liver, alcoholic liver fibrosis, alcoholic liver cirrhosis, and acute alcoholic hepatitis);" "It is an emergency antidote in the treatment of poisoning by radiotherapy (chemotherapeutic drugs, anti-tuberculosis drugs, neurolytic agents, antidepressants, analgesic and antipyretics);" "For treatment of vitamin C deficiency and prevention of scurvy;" "Glutathione for skin whitening has been shown to be safe and effective in numerous clinical studies;" and "results indicate that glutathione inhibits the synthesis and agglutination of melanin by interrupting the function of L-DOPA."
- **Saluta Glutathione Whitening kit:** "[I]s a full prescription drug;" "Higher glutathione levels are being linked to a healthier liver;" "new data is demonstrating that injectable glutathione serves as a potentially very effective treatment for Parkinson's disease;" and "Glutathione for skin whitening has been shown to be safe and effective in numerous clinical studies" and "results indicate that glutathione inhibits the synthesis and agglutination of melanin by interrupting the function of L-DOPA."
- **Laroscorbine Platinum Vitamin C with Collagen kit:** "Prévention de la carence en vitamin C collagen quand l'alimentation par vole orale est



impossible” translated in English as “Prevention of vitamin C collagen deficiency when feeding by oral means is not possible;” and “Contains 350mg of Collagen which has been shown to naturally firm and rejuvenate skin.”

18. Flawless Beauty promotes these unapproved new drugs on various websites including, but not limited to: [www.flawlessbeautyandskin.com](http://www.flawlessbeautyandskin.com) and

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[www.relumins.com](http://www.relumins.com). A link on the [www.flawlessbeautyandskin.com](http://www.flawlessbeautyandskin.com) website provides the consumer with directions for injecting the unapproved new drugs.

19. On March 27, 2014, a Flawless Beauty representative stated that the firm would stop selling and distributing the injectable drugs. However, on April 7, 2014, an FDA employee was able to purchase the Relumins Advanced Glutathione kits, and received written instructions using this injectable drug.

20. On March 31, 2014, the New Jersey Department of Health and Senior Services (“the state”) embargoed the injectable drug products at Flawless Beauty. The state temporarily lifted the embargo on May 16, 2014, to permit the company to voluntarily destroy some of the embargoed products and the LingZhi Capsules, which had not been embargoed. The state then reinstituted the embargo on the remaining sterile injectable drugs on the same day.

### **Claims For Forfeiture**

#### **COUNT I**

21. Incorporated herein and made part hereof are allegations contained in paragraphs 1 through 20 of this Complaint.



22. For the foregoing reasons, the defendant articles are unapproved new drugs introduced into interstate commerce in violation of section 21 U.S.C. § 355(a), because no person shall introduce or deliver for introduction into interstate commerce any new drug, unless an approval of an application filed pursuant to subsection (b) or (j) of this section is effective with respect to such drug, or the drug is the subject of an effective exemption from the approval requirement pursuant to 21 U.S.C. § 355(i).

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**COUNT II**

23. Incorporated herein and made part hereof are allegations contained in paragraphs 1 through 20 of this Complaint.

24. For the foregoing reasons, pursuant to 21 U.S.C. § 352(f)(1), the defendant articles are misbranded while held for sale after shipment in interstate commerce within the meaning of the Act, because the labeling fails to bear adequate directions for use and the articles are not exempt from that requirement, under 21 C.F.R. §§ 201.100(c)(2) and 201.115, because the articles lack approved applications.

**COUNT III**

25. Incorporated herein and made part hereof are allegations contained in paragraphs 1 through 20 of this Complaint.

26. For the foregoing reasons, pursuant to 21 U.S.C. § 352(o), the defendant articles are misbranded within the meaning of the Act because they were



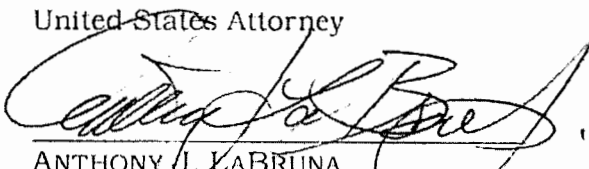


manufactured, prepared, or processed in an establishment not duly registered under 21 U.S.C. § 360.

**WHEREFORE**, the United States of America requests that the Court issue a warrant for the arrest *in rem* for seizure of the defendant articles; that notice of this action be given to all persons who reasonably appear to be potential claimants of the defendant articles; that the defendant articles be forfeited and condemned to the United States; that the defendant articles be disposed of as this Court may direct pursuant to the provisions of the Act; and that plaintiff be awarded its costs and disbursements in this action, and for such other and further relief as this Court deems proper and just.

PAUL J. FISHMAN  
United States Attorney

By:

  
ANTHONY J. LABRUNA  
Assistant United States Attorney



**VERIFICATION**

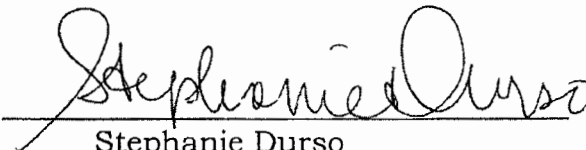
**STATE OF NEW JERSEY** :

**COUNTY OF ESSEX** :

I, Stephanie Durso, hereby verify and declare under penalty of perjury that I am a Compliance Officer, New Jersey District Office, United States Food and Drug Administration, that I have read the foregoing Verified Complaint *in rem* and know the contents thereof, and that the matters contained in the Verified Complaint are true to my own knowledge, except that those matters herein stated to be alleged on information and belief and as to those matters I believe them to be true.

The sources of my knowledge and information and the grounds of my belief are the official files and records of the United States, information supplied to me by other law enforcement officers, as well as my investigation of this case, together with others, as a Compliance Officer, New Jersey District Office, United States Food and Drug Administration.

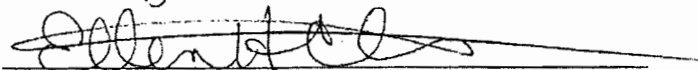
I hereby verify and declare under penalty of perjury that the foregoing is true and correct.



Stephanie Durso  
Compliance Officer  
United States Food and Drug

Administration

Sworn and subscribed to before me this 28<sup>th</sup> day  
of August, 2014, at Parsippany, New Jersey



Notary Public

